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SNAS
Reg. No. 575/P-051

Notified body 2854 | SKTC-180

bqs. s.r.o.
Studentska 12, 911 01
Trencin | Slovakia
www.bqsgroup.eu

EC Certificate IVDD 22 004 0138

EC Design-Examination Certificate

Directive 98/79/EC on In Vitro Diagnostic Medical Devices
Annex IV section 4

Certificate holder: **DIALAB Produktion und Vertrieb von chemisch - technischen Produkten und Laborinstrumenten Gesellschaft m.b.H**

IZ NOE-Sued Hondastrasse Objekt M55, A-2351 Wiener Neudorf, Austria

Other Facility(ies): -

The certificate was issued with respect to the following scope:

HBsAg Sensitive ELISA

This certificate is effective from 24 May 2022 until 26 May 2025 and remains valid subject to execution of regular examinations and continuous compliance.
Initial version of the certificate was effective from 24 May 2022.

Certification has been authorized by

Digitally signed by
Radovan Máčaj

Radovan Macaj
Head of Notified body

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Certified In Vitro diagnostic medical device

bqs issued the certificate on the basis of performed examination in accordance with Council Directive 98/79/EC, Slovak government decree No. 569/2001 Coll. of Laws and EN ISO/IEC 17065:2012. Notified Body has performed an examination of the design dossier in accordance with Annex IV section 4 of the directive and found that the design of the device conforms to the requirements laid down by Annex IV. For the placing on the market of List A devices an EC full quality assurance to Annex IV is required. Please see also notes overleaf if any.

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Additional information on certification

Related to certificate number:

IVDD 22 004 0138

Description of product(s) within the certification scope:

HBsAg Sensitive ELISA is an enzyme-linked immunosorbent assay (ELISA)for the qualitative detection of Hepatitis B surface antigen (HBsAg) in human serum or plasma. It is intended for the screening of blood donors and for the diagnosis of patients related to infection with Hepatitis B virus.

Types/Categories/Models:	Z12360 (96 wells)
Classification:	List A
Validity conditions:	-

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Initial version of the certificate was effective from 24 May 2022.

bqs.
Certified In Vitro diagnostic medical device

bqs issued the certificate on the basis of performed examination in accordance with Council Directive 98/79/EC, Slovak government decree No. 569/2001 Coll. of Laws and EN ISO/IEC 17065:2012. Notified Body has performed an examination of the design dossier in accordance with Annex IV section 4 of the directive and found that the design of the device conforms to the requirements laid down by Annex IV. For the placing on the market of List A devices an EC full quality assurance to Annex IV is required. Please see also notes overleaf if any.